

WHAT IS CLAIMED IS:

- 2 1. A monoclonal antibody for detecting urinary trypsin inhibitors in the
biological fluids of persons having disease, said antibody comprising an antibody
4 combining site which binds preferentially to at least one member of the group of urinary
trypsin inhibitors (UTI) consisting of AMBK, Bikunin, Uristatin, Uristatin-1, Uristatin-2
6 and fragments and aggregates thereof.
2. A monoclonal antibody of Claim 1 wherein said UTIs are Uristatin and
8 Uristatin-1 and -2.
3. A monoclonal antibody of Claim 1 wherein said monoclonal antibody is
10 secreted by hybridoma ATCC 421-5G8.1A8.5C1.
4. A monoclonal antibody of Claim 1 wherein said UTIs are Uristatin and
12 Uristatin-1 and -2 and said monoclonal antibody further binds to Tamm-Horsfall protein
(THF).
- 14 5. A monoclonal antibody of Claim 4 wherein said monoclonal antibody is
secreted by hybridoma ATCC 420-5D11.5G8.1E4.
- 16 6. A monoclonal antibody of Claim 1, wherein said monoclonal antibody
binds preferentially to the UTIs AMBK, Bikunin, Uristatin, and Uristatin 1 and 2 and
18 also to THP.
7. A monoclonal antibody of Claim 6 wherein said monoclonal antibody is
20 secreted by hybridoma ATCC 421-3G5.4C5.3B6.
8. A monoclonal antibody of Claim 1 for detecting UTI wherein said
22 biological fluid is urine.
9. A monoclonal antibody of Claim 1 for detecting UTI wherein said
24 biological fluid is blood.
10. A method of assaying a biological fluid for urinary trypsin inhibitors
26 (UTI) comprising contacting a sample of biological fluid with at least one monoclonal
antibody capable of binding to urinary trypsin inhibitors characterizing said biological
28 fluid of persons having disease and identifying the bound UTIs.
11. A method of Claim 10 wherein said urinary trypsin inhibitors
30 characterizing the urine of persons having disease are members of the group consisting
of AMBK, Bikunin, Uristatin, Uristatin-1, Uristatin-2, and fragments and aggregates
32 thereof.

12. A method of Claim 11 wherein said monoclonal antibody binds preferentially to the UTIs Uristatin, Uristatin-1 and -2, and also to Tamm-Horsfall protein (THP).
13. A method of Claim 12 wherein said monoclonal antibody binds preferentially to the UTIs Uristatin and Uristatin-1 and -2.
14. A method of Claim 11 wherein said monoclonal antibody binds to the UTIs AMBK, Bikunin, Uristatin, and Uristatin-1 and -2 and also to THP.
15. A method of Claim 12 wherein said monoclonal antibody is secreted by hybridoma ATCC 420-5D11.5G8.1E4.
16. A method of Claim 13 wherein said monoclonal antibody is secreted by hybridoma ATCC 421-5G8.1A8.5C1.
17. A method of Claim 14 wherein said monoclonal antibody is secreted by hybridoma ATCC 421-3G5.4C5.3B6.
18. A method of Claim 10 wherein said UTIs are identified in an immunoassay.
19. A method of Claim 18 wherein said immunoassay is selected from the group consisting of MR, LAI, IC, RIA, ELISA, EIA, FIA, LIA, CLA, OA, and rare earth metals label assays, as defined herein.
20. A method of Claim 10 wherein said biological fluid is urine.
21. A method of Claim 10 wherein said biological fluid is blood.
22. A method of Claim 10 wherein a UTI is measured directly by a monoclonal antibody.
23. A method of Claim 10 wherein all UTIs are measured by a first monoclonal antibody and specific UTIs measured by a second antibody are subtracted from the UTIs measured by the first antibody to measure the UTIs found by first antibody but not by the second antibody.
24. A method of Claim 22 wherein said antibody measures Uristatin-1 and/or Uristatin-2.
25. A method of Claim 22 wherein said antibody measures all UTIs but not the pro-inhibitors.
26. A method of Claim 23 wherein said first antibody measures Uristatin-1 and/or Uristatin-2 and said second antibody measures all UTIs and Bikunin and AMBK are measured by difference.

27. A method of Claim 23 wherein said first antibody measures all
2 UTIs and THP and said second antibody measures THP and UTIs are measured by
difference.

4 28. A method of assaying a biological fluid for urinary trypsin inhibitors
(UTI) comprising the steps of:

6 (a) adding a biological fluid sample suspected of containing urinary
trypsin inhibitors to a substrate;

8 (b) adding to said sample of (a) monoclonal antibodies capable of
binding to urinary trypsin inhibitors characterizing the biological fluid of humans having
10 disease;

(c) adding to the combined monoclonal antibodies of (b) and the urine
12 sample of (a) a ligand capable of binding to said monoclonal antibodies, said ligands
being bound to an enzyme;

14 (d) washing from the combined monoclonal antibodies of (b), the
biological fluid sample of (a) and the ligand of (c) the portion of said ligand unbound to
16 said monoclonal antibodies;

(e) determining the amount of said urinary trypsin inhibitors bound to
18 said monoclonal antibodies and said ligands by adding a reporter molecule capable of
developing a signal by reaction with said enzyme and correlating the signal developed
20 with the amount of said urinary trypsin inhibitors.

29. A method of Claim 28 wherein said urinary trypsin inhibitors
22 characterizing the biological fluid of persons having disease comprise at least one
member of the group consisting of AMBK, Bikunin, Uristatin, Uristatin-1, Uristatin-2
24 and fragments and aggregates thereof.

30. A method of Claim 29 wherein said monoclonal antibody binds
26 preferentially to the UTIs Uristatin, Uristatin-1 and -2, and also to Tamm-Horsfall
protein (THP).

28 31. A method of Claim 29 wherein said monoclonal antibody binds
preferentially to Uristatin and Uristatin-1 and -2.

30 32. A method of Claim 29 wherein said monoclonal antibody binds
preferentially to the UTIs AMBK, Bikunin, Uristatin, and Uristatin-1 and -2 and also to
32 THP.

23. A method of Claim 30 wherein said monoclonal antibody is
2 secreted by hybridoma ATCC 420-5D11.5G8.1E4.
34. A method of Claim 31 wherein said monoclonal antibody is secreted by
4 hybridoma ATCC 420-5G8.1A8.5C1.
35. A method of Claim 32 wherein said monoclonal antibody is secreted by
6 hybridoma ATCC 421-3G5.4C5.3B6.
36. A method of Claim 28 wherein said biological fluid is urine.
- 8 37. A method of Claim 28 wherein said biological fluid is blood.
38. A method of Claim 28 wherein a UTI is measured directly by a
10 monoclonal antibody.
39. A method of Claim 28 wherein all UTIs are measured by a first
12 monoclonal antibody and specific UTIs measured by a second antibody are subtracted
from the UTIs measured by the first antibody to measure to UTIs found by the first
14 antibody but not by the second antibody.
40. A method of Claim 38 wherein said antibody measures Uristatin-1 and/or
16 Uristatin-2.
41. A method of Claim 38 wherein said antibody measures all UTIs but not
18 the proinhibitors.
42. A method of Claim 39 wherein said first antibody measures Uristatin-1
20 and/or Uristatin-2 and said second antibody measures all UTIs and Bikunin and AMBK
are measured by difference.
- 22 43. A method of Claim 39 wherein said first antibody measures all UTIs and
THP and said second antibody measures THP and UTIs are measured by difference.